## **REMARKS**

The Examiner rejected claims 1 and 4 under 35 U.S.C. § 102(b) as being anticipated by Kater (5,046,509). Specifically, the Examiner incorrectly states that the Kater device is provided with a "sleeve 112 that is slidably coupled to the outer surface of the elongated tube" 100. Kater does not teach or otherwise disclose a sleeve or a gasket that is slidably coupled with a tube. Rather, the Kater specification, at column 3, lines 20-24, states that

the cylindrical seal 108 includes a central aperture 110 within which the mounting end 104 of the needle 100 is <u>fixedly attached</u>. Furthermore, the cylindrical seal 108 is <u>fixedly attached</u> to a needle receiving end 112 of the first connector member 106.

Clearly, the Kater device is provided with a needle or tube that is in a fixed, non-sliding engagement with a seal, which is in a fixed, non-sliding engagement with the sleeve. Applicant's device, however, clearly teaches and claims a sleeve and sealing gasket that are slidably engaged with the outer surface of the tube in a manner that permits selective, sliding movement of the sleeve and gasket along a length of the tube's outer surface.

The Examiner further argues that he is "interpreting the claimed elements 'sleeve that is slidably coupled' in this way: since the tube and gasket and sleeve are all separate elements, the gasket must inherently be 'slidably mounted' along with the sleeve on the tube." The Examiner then states that "according to Microsoft Bookshelf Dictionary the definition of *coupled* is: two things connected together. Thus, 'attached' can be considered synonymous as connected together." The Examiner's argument is unclear and fails to address the issue of the relative movement enabled by the

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connection between the gasket and sleeve with the tube of applicant's invention. Claim 1 does not include a limitation that reads, in part, "sleeve that is slidably coupled." However, in an effort to clarify the matter and expedite the prosecution of this matter, claim 1 has been amended to specifically claim the structural and sliding engagement between the components of the applicant's invention. Accordingly, claim 1 is believed to be allowable, since a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal, Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 4 depends from claim 1 and is believed to be allowable for at least the reasons set forth hereinabove with respect to claim 1. Applicant respectfully disagrees with the Examiner's position that a taper in an end portion of a tube is the same as angularly disposing the end of the tube with respect to the body of the tube. However, Claim 4 has been amended to specifically state that the "tube is provided with an angular bend, adjacent the distal end of said tube, so that the open interior portion of said tube extends along a non-linear path between said proximal and distal ends." The hollow interior portion of the needle disclosed by Kater is linear from one end to its opposite end. Accordingly, claim 4 is believed to be allowable.

The Examiner rejected claim 8 under 35 U.S.C. § 102(b) as being anticipated by Kramer et al. (4,969,870). The applicant respectfully disagrees with the rejection. The Examiner states that Kramer et al. teach a device having a sleeve 19 that is slidably coupled to the outer surface of the tube 15. However, the figures within the Kramer

reference clearly show that the tube 15 is attached in a fixed position within a handle 31, which is slidably disposed within the sleeve 19. Accordingly, the sleeve is not slidably coupled to the outer surface of the tube. If, for sake of argument the lower portion 43 of the handle 31 were deemed to be the "tube", the reference still wouldn't read on the claim due to the fixed engagement between the sleeve and the tube. Moreover, the distal end of the tube in that situation would not be capable of being positioned within the bone while the sealing surface was positioned outside the bone, as claimed within claim 8, due to positive stop within the base 19. Applicant has amended claim 8, however, to clarify the limitations previously set forth. The examiner is respectfully requested to reconsider the aforementioned rejection and allow claim 8.

The Examiner has rejected claims 2 and 5 under 35 U.S.C. § 103(a) as being unpatentable over the Kater reference in view of Lee et al. (5,693,030). The Examiner states that Kater fails to teach openings in the distal end of the tube or the use of an obturator but that the Lee reference teaches such structures. Similarly, the Examiner has rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Kater in view of Dubinsky (WO 99/52441). Specifically, the Examiner states that Kater fails to teach a tube having an arcuate portion, as shown in Dubinsky. Applicant respectfully disagrees. Claims 2, 3 and 5 depend from claim 1 and are believed to be allowable for at least the reasons set forth hereinabove with respect to claim 1.

Moreover, in determining the difference between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983). A prior art reference and the claimed invention must be considered in their entireties. Distilling an invention down the "jist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), Cert. denied, 469 U.S. 851 (1984).

The mere fact that the references can be modified does not render the resulting modified structure obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). "A statement that modifications of the prior art meet the claimed invention and would have been 'well within the ordinary skill in the art at the time the claimed invention was made because the references relied upon teach that all aspects of the claimed invention were individually known in the art' is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." Ex parte Leavengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

Just because a structural detail is simple and known for other purposes, does not render it "obvious". In re Kotzab, 217 F.3d 1365, 55 USPQ2d 1313 (Fed. Cir. 2000), the Federal Circuit Court of Appeals decided that the control of multiple valves by a single sensor rather than by multiple sensors was a technologically simple concept. However, the Federal Circuit held that there was no finding as to the specific understanding or principal within the knowledge of the skilled artesian that would have provided the motivation to use a single sensor as the system to control more than one valve. The

claimed structural design of applicant's device is an example of such a patentable structure born from a technologically simple concept. More importantly, there is no teaching or suggestion that would render the claimed combination of elements "obvious". Ex parte Leavengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). Accordingly, the combinations of claimed elements within claims 2, 3 and 5 are believed to be patentable and the Examiner is respectfully requested to reconsider the aforementioned rejections and to allow claims 2, 3 and 5.

In light of the above amendments and remarks, applicant asserts that the claims are in condition for allowance. Applicant respectfully requests reconsideration and allowance of the same.

No fees or extensions of time are believed to be due in connection with this amendment; however, please consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 502093.

Respectfully submitted,

SHANE M. NIEBERGAL Registration No. 44,974

THOMTE, MAZOUR & NIEBERGALL

Attorneys of Record

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2120 South 72nd Street, Suite 1111 Omaha, NE 68124 (402) 392-2280



## **CERTIFICATE OF MAILING**

I hereby certify that the original of this SECOND AMENDMENT AFTER FINAL REJECTION for R. MICHAEL GROSS, Serial No. 10/046,592, was mailed by first class mail, postage prepaid, to Mail Stop RCE along with the RCE attached hereto, to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this /// day of July, 2005.